

**Written Testimony of Katherine Eban**

**Investigative Journalist, Author of Dangerous Doses:**

**How Counterfeiters are Contaminating America's Drug Supply,**

**May 2005, Harcourt Inc.**

**For the Subcommittee on Criminal Justice, Drug Policy and Human  
Resources**

**Government Reform Committee**

**"Sick Crime: Counterfeit Drugs in the United States,"**

**November 1, 2005**

Mr. Chairman and members of the committee, thank you for your commitment to safeguard the nation's medicine. As an investigative journalist and book author, I spent the last three years documenting a rising tide of counterfeit medicine in the nation's pharmacies and hospitals. My book on this topic, *Dangerous Doses: How Counterfeiters are Contaminating America's Drug Supply*, was published in May by Harcourt. It chronicles the work of a Florida task force, Operation Stone Cold, whose findings led to the overhaul of Florida's drug-supply laws, making them the toughest in the country.

My findings in *Dangerous Doses* are based on more than 160 significant interviews. I also obtained more than 13,000 pages of documents. Many of the incidents I describe in the book I witnessed first hand.

My investigation revealed that a stream of adulterated medicine, traded by felons and accompanied by false paperwork, routinely lands on our pharmacy shelves. This happens in part because major wholesalers seek out discounted medicine from small secondary wholesalers. This extremely dangerous "trading" between wholesalers has degraded our medicine and endangered consumers.

In 2003, this trading allowed counterfeit Lipitor to reach some 600,000 patients. In 2002, 110,000 vials of counterfeit Epogen and Procrit, lifesaving injectable medicine, entered the supply chain and reached patients including Tim Fagan in New York and Maxine Blount in Missouri. Last year, patients undergoing hernia surgery were implanted with counterfeit and non-sterile Prolene mesh. At least one suffered horrible complications from a recurring infection.

Despite recent positive efforts by some manufacturers, wholesalers, pharmacy chains and states to tighten the supply chain, the problem is no less urgent today. As we meet here, 1,000 Exxon Mobil employees are absorbing the news that they were recently injected with counterfeit flu vaccine at a company health fair.

How does this happen?

Because our supply chain is porous and minimally-regulated, our medicine may move through a dozen hands on its way from the manufacturer to the pharmacy. The "wholesalers" who buy and sell it along the way may be narcotics traffickers, mafia members or common criminals. Though these individuals call themselves wholesalers or distributors, many never buy directly from manufacturers and never sell directly to pharmacies. They are middlemen, who buy and sell medicine to one another in a process that resembles an all-hours auction. Every single counterfeit to reach American patients has first moved through their hands, and comes with scant proof of its origin or purity. Who in their right mind would buy this medicine? Everyone, unfortunately. Finding their discounts irresistible, even the nation's major wholesalers set up "trading divisions" to scout for bargains from these secondary wholesalers. Those purchases have allowed medicine that is recycled, stolen, expired, subpotent, mishandled and even counterfeit to reach patients.

Our drug supply remains vulnerable despite some recent reforms. Since my book's publication, two of the nation's largest wholesalers, Cardinal Health and AmerisourceBergen, made important announcements: Cardinal that it would close its trading division and limit purchases from secondary wholesalers; Amerisource that it would no longer buy secondary-source drugs for American consumers. The CVS pharmacy chain has also said that it will no longer buy from distributors who purchase pharmaceuticals from the secondary market.

But loopholes remain. Because our distribution system is national and medicine that is in California one day could wind up in New York or Missouri the next, our drug supply is only as clean as its dirtiest link. Even when Florida overhauled its laws in 2003, several rogue wholesalers left the state and set up shop in North Carolina and elsewhere.

The American pharmaceutical market has become a profit center for counterfeiters and the criminals who traffic in their products. With soaring prices, weak laws and numerous opportunities for arbitrage, narcotics traffickers have taken note: they can make as much, if not more, dealing in cancer and AIDS medicine. Their deterrents? Minimal jail sentences and nominal fines.

In many states, minimal regulations make it easy for almost anyone to become a pharmaceutical wholesaler. Before Florida changed its laws, its Bureau of Statewide Pharmaceutical Services required that applicants fill out a three-page form with a question: have you ever been convicted of a felony? Felons checked the "No" box, and the Bureau did not check their criminal backgrounds. Consequently, the state of Florida issued pharmaceutical wholesaling licenses to convicted narcotics traffickers, and their medicine reached patients across the country.

While reporting *Dangerous Doses*, I determined to learn how the counterfeit Epogen that Tim Fagan received made its way to a CVS Pharmacy in Long Island. In the attached chart, I document the likely path Tim Fagan's medicine took, a route that took me over two-and-a-half years to reconstruct. His medicine, which requires constant refrigeration and stable handling, was unlabeled by a counterfeiter, transported in used paint cans and blazing car trunks and was allegedly stored in a beer cooler in a Miami strip club.

His medicine, made by Amgen, began as 2,000 U/ml Epogen. The distributors Cardinal Health and AmerisourceBergen sold 110,000 vials of it to a small Miami pharmacy, J&M Pharmacare. Though this no-name pharmacy bought an amount that could have stocked a chain of oncology hospitals – a strong signal that the pharmacy was intending to divert it -- the major wholesalers did not take note. The pharmacy never dispensed it to a single patient. Instead, it sold all the medicine to a man who had ordered it on behalf of the alleged counterfeiter, a former body builder named Jose Grillo.

Grillo packed the low-dose Epogen vials into paint cans and carried them to a South-Miami trailer, where a friend of his soaked the vials overnight in his back yard, rubbed off the low-dose labels and glued on fake high-dose ones for 40,000 U/ml. The setting

was as far from sterile and controlled as one could possibly imagine. But the math was compelling: Grillo had allegedly transformed each \$25 vial into a \$470 vial, a scheme that was worth \$46 million.

Once he had unlabeled the vials, Grillo is alleged to have brought them to his customers, which included a strip club in Miami, and sold the medicine for one-sixth the average wholesale cost. Investigators believe that the club's owners bought the medicine and stored it in a beer cooler in a back room. They in turn are alleged to have sold it to their customers.

The medicine then moved through a network of shell companies, some with legitimate licenses, some without. Some \$20 million of the medicine is believed to have moved through a licensed wholesaler run by an eighth-grade dropout and heroin addict with a rap sheet that included kidnapping and aggravated battery. As a Florida grand jury noted, these are people you wouldn't trust to mow your lawn, let alone handle your medicine. Tim's medicine moved through seven sets of hands before even reaching a company legitimately licensed to distribute it.

The local wholesaler AmerRx sold it to a regional wholesaler, Dialysist West, which then contacted AmerisourceBergen with a seemingly lucky offer: high-dose Epogen for a price lower than the manufacturer's. Amerisource bit, buying back the very low-dose Epogen it had originally sold, but which had been counterfeited in the interim.

Despite the important changes announced by Amerisource, Cardinal and CVS, I contend that the same thing could happen today. Numerous secondary wholesalers are still in operation, peddling substandard medicine to their customers, namely anyone seeking a discount and willing to take the risk.

What can we do about this? I propose that we need strong federal regulations to close these loopholes and protect consumers and urge the committee to look at Tim Fagan's Law, H.R. 2345, introduced by the Fagan's congressman Rep. Steve Israel of Long Island. It proposes strict regulation of wholesalers, severe criminal penalties for those who counterfeit medicine, or knowingly traffic in it. It requires old-fashioned paper pedigree records to document each step our medicine takes. It allows for stronger enforcement and increased funding for the FDA's office of criminal investigations, and gives the FDA the recall authority that it now lacks.

It was an honor to appear before this committee. I appreciate your commitment to protecting America's drug supply.

For more information on Dangerous Doses, counterfeit drugs and other links, please visit [www.dangerousdoses.com](http://www.dangerousdoses.com), or e-mail Katherine Eban at [keban@dangerousdoses.com](mailto:keban@dangerousdoses.com).